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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,471	08/27/2001	William J. Rissmann	032580.0018.UTL	5252
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CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER DROESCH, KRISTEN L	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/940,471

Applicant(s)

RISSMANN ET AL.

Examiner

Kristen Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/21/04 (response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 191-217 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 195,201-206,208,209,211-214,216 and 217 is/are allowed.
- 6) ☒ Claim(s) 191-194,196-200,207,210 and 215 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The indicated allowability of the subject matter of claim 195 including “sensing an abnormality further includes determining whether the patient has an abnormally slow heart rate” is withdrawn in view of the newly reconsidered reference(s) to Causey III (5,411,547) and Dahl et al. (5,230,337). Rejections based on the newly reconsidered reference(s) follow.

The finality of the last office action is withdrawn.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 191-194, 196-200 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 191 recites the limitation "the step of sensing an abnormality" in line 10.

There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 191-192 are rejected under 35 U.S.C. 102(b) as being anticipated by Causey III (5,411,547).

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With respect to claim 191, Causey III shows a method of supplying energy for alleviating a cardiac dysfunction comprising: implanting a device having a power source and an energy storage system into a patient; providing a lead system having one or more electrodes, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart; coupling the power source to the energy storage system; storing energy in the energy storage system; and discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode (24, 26) disposed in the lead system; wherein the step of sensing an abnormality further includes determining whether the patient has an abnormally slow heart rate (asystole) (Col. 1, lines 36-39; Col. 3, lines 28-53) (Fig. 4).

Regarding claim 192, Causey III shows providing a lead system such that it does not reside in the patient's vasculature (Fig. 4).

6. Claims 207, 210, and 215 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahl et al. (5,230,337).

With respect to claim 207, Dahl et al. shows a method comprising providing a lead assembly including a first electrode (188, 190) implanted in a patient, the lead assembly is provided such that it does not contact the patient's heart; providing a device including a battery, and means for storing energy coupled to the lead assembly; providing a second electrode (188, 190) implanted in the patient such that it does not contact the patient's heart; sensing far-field signals using a sensing electrode pair (188, 190); determining if the patient's heart rhythm requires electrical treatment; supplying energy from the battery to the energy storage means and discharging the energy stored to the patient using a stimulus electrode pair (188, 190) wherein the step of providing the lead

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system includes providing a lead extending medially from the device. (Col. 1, lines 20-30; Col. 9, line 52- Col. 10, lines 6; Fig. 22).

Regarding claim 210, Dahl et al. shows implanting the device between approximately the third rib and the twelfth rib of the patient (Fig. 22).

With respect to claim 215, Dahl et al. shows providing a lead assembly outside of the patient's vasculature (Fig. 22).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 193-194, and 196-199 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey III (5,411,547) and further in view of Yang (5,476,503). Causey III is as explained before. Although Causey III fails to show sensing the abnormality in the patient's cardiac rhythm using electrodes disposed internally to the patient but not contacting the patient's heart, attention is directed to Yang, which teaches a defibrillation electrode including sensor electrodes (Fig. 2; Col. 5, lines 40-46). Yang teaches that the defibrillation electrode including sensor electrodes allows for a substantial increase in the capabilities of the defibrillator and allows the sensing of normal cardiac depolarization activity and abnormal depolarization cardiac activity (Col. 5, lines 47-52). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the electrode of Causey III to include sensing electrodes or sensing capabilities and allow for sensing an abnormality in the

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patient's cardiac rhythm using electrodes disposed internally to the patient but not contacting the patient's heart as Yang teaches in order to allow a substantial increase in the capabilities of the defibrillator and the sensing of normal cardiac depolarization activity and abnormal depolarization cardiac activity.

With respect to claims 196-197, Causey III further shows determining if the patient has an abnormally fast heartbeat or determining if the patient is likely experiencing defibrillation (Col. 1, lines 36-39).

Regarding claim 198, Causey III shows the electrodes (24, 26) are part of the lead system (Fig. 4).

With respect to claim 199, Causey III shows at least one of the electrodes (24, 26) in the lead system is also an electrode used for discharging energy (Fig. 4).

9. Claim 200 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III (5,411,547) in view of Bardy (5,292,338). Causey III is as explained before. Causey fails to specifically point out that the defibrillator is implanted subcutaneously between the third rib and the twelfth rib of the patient, but only mentions that a known defibrillator is used. Attention is directed to Bardy, which teaches a known defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the known defibrillator Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Causey III

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subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

***Response to Arguments***

10. Applicant's arguments with respect to claims 191-194, 196-200, 207, 210, and 215 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

11. Claims 195, 201-206, 208, 209, 211-214, and 216-217 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

kld

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